



DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

#21

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Food and Drug Administration
Rockville MD 20857

Re: New Jersey Meniscal
Bearing Knee Replacement
Docket No. 85E-0296

Mr. Charles E. Van Horn
Director, Patent Examining Group 120
U.S. Patent and Trademark Office
Washington, DC 20231

Dear Mr. Van Horn:

This is in regard to the application for patent extension for U.S. Patent No. 4,309,778, filed by Biomedical Engineering Trust, under 35 U.S.C. § 156. The medical device claimed by the patent is the New Jersey Meniscal Bearing Knee Replacement.

In the August 30, 1985 issue of the Federal Register, the Food and Drug Administration published its determination of the product's regulatory review period, as required under 35 U.S.C. § 156(d)(2)(A). That notice provided that on or before February 26, 1986, 180 days after the publication of the determination, any interested person could file a petition with FDA under 35 U.S.C. § 156(d)(2)(B)(i) for a determination of whether the patent extension applicant acted with due diligence during the regulatory review period.

The 180-day period for filing a due diligence petition pursuant to the notice regarding the New Jersey Meniscal Bearing Knee Replacement has expired and FDA has received no such petition. FDA therefore considers its determination of the regulatory review period for the New Jersey Meniscal Bearing Knee Replacement final.

Please let me know if we can provide further assistance.

Sincerely yours,

Ronald L. Wilson
Director
Health Assessment Policy Staff
Office of Health Affairs

cc: John G. Gilfillian III
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